

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

Appln. No. : 10/792,178 Confirmation No.: 4900
Applicant : David E. Francischelli et al.
Filed : March 3, 2004
TC/A.U. : 3769
Examiner : Henry M. Johnson, III
Docket No. : P008575.06/ M190.253.101
Customer No. : 77218
Title : VIBRATION SENSITIVE ABLATION DEVICE AND
METHOD

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
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Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on March 14, 2011, appealing the final rejection of claims 25-33 of the above-identified application as set forth in the Final Office Action mailed December 13, 2010.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 012525 in the amount of \$540.00 for filing a Brief in Support of an Appeal as set forth under 37 C.F.R. § 41.20(b)(2). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 012525.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 25-33.

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

TABLE OF CONTENTS

Real Party in Interest.....	3
Related Appeals and Interferences.....	3
Status of Claims	3
Status of Amendments	3
Summary of The Claimed Subject Matter	3
Grounds of Rejection to be Reviewed on Appeal.....	
Argument	
Conclusion	
Claims Appendix	
Evidence Appendix.....	
Related Proceedings Appendix.....	

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc., of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

The present application had been appealed, and the Panel Decision mailed on September 1, 2010, reversed the rejection of the claims but entered a new ground of rejection.

In a related case, a Notice of Appeal had been filed in a division application, U.S. Patent Serial No. 11/648,976, but Appellants have reopened prosecution in that case with a Request for Continued Examination and amendment filed May 2, 2011.

STATUS OF CLAIMS

The application had included claims 1-79. Claims 1-24 and 34-61 were canceled and claims 62-79 were withdrawn from further consideration during prosecution as a result of restriction requirements. Claims 25-33 remain pending and are the subject of this Appeal.

STATUS OF AMENDMENTS

No Amendments have been filed subsequent to the Final Office Action mailed on December 13, 2010.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The Summary is set forth as exemplary embodiments corresponding to the language of independent claim 25. Discussions about elements of claims 25 can be found at least at the cited locations in the specification and drawings.

Independent claim 25, is a directed to method of ablating organic tissue, comprising:
positioning an electrode adjacent the organic tissue (page 6, lines 27-28);
supplying electrical power to the electrode (page 6, lines 28-29) to effect ablation of the organic tissue (page 7, line 1);

sensing with a sensor (page 9, lines 18-19) positioned adjacent the electrode (page 8, lines 28-29, page 9, lines 3-4; Figure 2) the vibration of the organic tissue being ablated (page 8, 29-30) wherein the vibration is self-generated in the organic tissue in response to the

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

ablation and the vibration occurs prior to substantial boiling (page 3, lines 20-31; page 10, lines 21-25) to water in the organic tissue (page 11, lines 23-24); and

reducing power to the electrode when the vibration reaches a given value (page 10, lines 25-28; page 11, lines 3-4).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 25-26 and 28-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nardella, U.S. Patent No. 5,733,281 ("the Nardella '281 Patent").

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Nardella '281 Patent in view of Nardella, U.S. Patent No. 5,334,193 ("the Nardella '193 Patent").

ARGUMENT

I. The Applicable Law

To anticipate a claim under 35 U.S.C. 102, a reference must teach every limitation of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 [2 USPQ2d 1051, 1053] (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). *See also Atlas Power Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 [51 USPQ2d 1943, 1946] (Fed. Cir. 1999).

With regard to a 35 U.S.C. § 103 obviousness rejection: "Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in *each and every case*." M.P.E.P. 2141 (*emphasis in the original*). The Examiner bears the burden under 35 U.S.C. § 103 in establishing a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 [5 USPQ2d 1596, 1598] (Fed. Cir. 1988).

One criterion that must be satisfied to establish a *prima facie* case of obviousness is that the reference or combined references must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981 [180 USPQ 580] (C.C.P.A. 1974).

However, "[a] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1731 [82 USPQ2d 1385, 1389] (2007). In making an obviousness determination over a combination of prior art references, it is "important to

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* at 1738 [1396].

In order to facilitate review of the determination of whether there was an apparent reason to combine known elements in the fashion claimed by the patent at issue, the “analysis should be made explicit.” *Id.* at 1738 [1396]. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (Fed. Cir. 2006) (cited with approval in *KSR*, 127 S. Ct. at 1738 [82 USPQ2d at 1396])

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 [227 USPQ 543, 551] (Fed. Cir. 1985). Furthermore, claims must be interpreted in light of the specification, claim language, other claims, and prosecution history. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 [1 USPQ2d 1593, 1597] (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). At the same time, a prior patent cited as a § 103 reference must be considered in its entirety, “*i.e.* as a *whole*, including portions that lead away from the invention.” *Id.* That is, the Examiner must recognize and consider not only the similarities, but also the *critical differences between the claimed invention and the prior art* as one of the factual inquiries pertinent to any obviousness inquiry under 35 U.S.C. § 103. *In re Bond*, 910 F.2d 831, 834 [15 USPQ2d 1566, 1568] (Fed. Cir. 1990) (*emphasis supplied*).

Furthermore, the Examiner must avoid hindsight. *Id.* “A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 127 S. Ct. at 1739 [82 USPQ2d at 1397] (citing to *Graham v. John Deere*, 383 U.S. 1 [148 USPQ 459] (1966) in warning against a temptation to read into the prior art the teachings of the invention at issue and instructing courts to guard against slipping into the use of hindsight).

“[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR*, 127 S. Ct. at 1737 [82 USPQ2d at 1395] (citing to *United States v. Adams*, 383 U.S. 39, 51-52 [148 USPQ 479] (1966)).

In conclusion, an Appellant is entitled to a patent grant if a *prima facie* case of

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

obviousness is not established. The Federal Circuit has endorsed this view in stating: “If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the Appellant is entitled to grant of the patent.” In re Oetiker, 977 F.2d 1443, 1446 [24 USPQ2d 1443, 1448] (Fed. Cir. 1992).

II. Rejection of Claims 25-26 and 28-33 under 35 U.S.C. 102(b) as being anticipated by the Nardella ‘281 Patent.

Claims 25-26 and 28-33 were rejected as being anticipated by the Nardella ‘281 Patent. Claim 25 is an independent claim, and claims 26 and 28-33 depend from claim 25.

A. Procedural Background of the Appeal

The Nardella ‘281 Patent teaches two stages of a feedback system for use with electrosurgical instruments, including an impedance determination stage 30 and an acoustic stage 50. The impedance stage 30 includes a system that determines the impedance between electrodes and generates an impedance output signal that is conveyed to an electrosurgical generator. The features of the impedance stage 30 have largely been ignored in the Office Actions and the Panel Decision, and Appellants submit the features of the impedance stage do not apply to the pending claims.

The acoustic stage 50, however, has been the subject of the Office Actions and the Panel Decision with respect to the pending claims. The acoustic stage 50 includes two aspects, i.e., an ultrasonic transducer embodiment indicated in Figure 2 of the Nardella ‘281 Patent and accompanying text and a microphone embodiment indicated in Figure 3 of the Nardella ‘281 Patent and accompanying text.

In the ultrasonic transducer embodiment, the acoustic stage 50 induces an ultrasonic transducer to resonate and produce ultrasonic waves. “These waves are typically reflected by the tissue or other components in the vicinity of the tissue, e.g., steam or other gases, and are received by the transducer 20, which produces corresponding electrical signals that are received and processed by the acoustic stage 50.” The Nardella ‘281 Patent at column 4, lines 50-54.

Independent claim 25 includes the features of “sensing with a sensor positioned adjacent to the electrode the vibration of the organic tissue being ablated wherein the vibration is self-generated in the organic tissue in response to the ablation.” In response to

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

the rejection of the claims based on the ultrasonic transducer embodiment, the Panel Decision states at page 3,

We are generally in agreement with Appellants' arguments . . . that Nardella '281 uses an ultrasonic oscillator which sense reflected waves off the tissue to detect steam or other gases. Consequently, we agree that the oscillator does not receive only vibrations of the organic tissue that are self-generated in response to the ablation. Therefore, the Examiner's rejection under § 102 of this embodiment is reversed.

In the microphone embodiment, a microphone is used to detect sounds at the surgical site. A speaker transforms signals carried by the microphone into audible signals, and an acoustic analyzer circuit can be disposed between the microphone and the speaker to analyze the acoustic waves received by the microphone. *See*, the Nardella '281 Patent at column 8, line 63 to column 9, line 4. The microphone embodiment is also addressed in the Panel Decision, which states at page 3,

The microphone receives vibrations of acoustic waves self-generated by the tissue and communicates these waves not only to a speaker 180 but also by a conductor 188 to control an RF generator. . . . Nardella '281 makes clear that the microphone is responding, not to the presence of steam, but to the noise generated when steam is created.

While the Panel Decision reversed the rejection based on the ultrasonic transducer embodiment, it denominated a new ground of rejection of the pending claims based on the microphone embodiment and allowed Appellants an opportunity to respond.

B. The Present Claims are Distinguishable from the Nardella '281 Patent

Independent claim 25 has been amended during the prosecution subsequent to the Panel Decision. Claim 25 is directed toward "A *method* of ablating organic tissue" (*emphasis supplied*). Claim 25 still includes the features of "sensing with a sensor positioned adjacent to the electrode the vibration of the organic tissue being ablated wherein the vibration is self-generated in the organic tissue in response to the ablation" and "reducing power to the electrode when the vibration reaches a given value." Accordingly, Appellants maintain the claims are distinguishable from the ultrasonic transducer embodiment of the Nardella '281 Patent. Claim 25 now also includes the features of "and the vibration occurs prior to substantial boiling of water in the organic tissue."

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

The Final Office Action mailed on December 13, 2010, rejected the claims based on the Nardella '281 Patent. In response to the amended features of claim 25, the Final Office Action states, "Nardella teaches the power may be reduced when the steam is above a selected level, thus teaching the vibrations are associated with levels of steam generation and are interpreted as including the period before a boiling point as Nardella is concerned with the effects of steam generation and tissue 'pops'." (citations omitted). Appellants traverse this argument and submit that the Nardella '281 patent does not teach, and the prior art does not make obvious, the features of the independent claim 25.

The microphone embodiment as explained at column 8, lines 64-65, is used to detect sounds at the surgical site and convert them into electrical signals. The Nardella '281 Patent states the electrical signals from the speaker can be conveyed to the generator 40 along conductor 188 as described at column 9, lines 22-23 and as shown in Figure 3. At column 9, lines 24-26, the Nardella '281 Patent states, "The generator, in response to the magnitude of the signal, can regulate the amount of power supplied to the energy delivering electrode 12."

With respect to the particular sounds of interest detected and analyzed by the microphone embodiment, the Nardella '281 Patent states at column 9, lines 36-39, "The creation of steam at the surgical site also produces characteristic sounds that are detected by the microphone 170 and conveyed by the clinician by speaker." In particular, "the creation of high levels of steam have associated therewith higher level of noise, and vice versa. Thus, the clinician can audibly monitor the relative levels of steam by monitoring the sound levels associated therewith." The Nardella '281 Patent at column 9, lines 39-44. In summary, while the Nardella '281 Patent teaches a *device* that includes a microphone to detect sounds proximate the ablation site, the *method* taught in the Nardella '281 Patent teaches listening for sounds indicative of relative levels of steam creation and adjusting power accordingly.

The method of claim 25 is not taught in the Nardella '281 Patent. For example, the claims require "sensing the vibration . . . wherein . . . the vibration occurs prior to substantial boiling" and "reducing power to the electrode when the vibration reaches a given value." In order to effect meaning to the claim, the sensed vibration at the given value is still vibration prior to substantial boiling. In as much as the Final Office Action states, "the vibrations are associated with levels of steam generation and are interpreted as including the period before boiling as Nardella is concerned with the effects of steam generation," the method set forth in claim 25 is not concerned with levels of steam. There is simply no teaching in the Nardella

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

‘281 Patent in the passages set forth above or elsewhere in the reference that the method (1) detects sounds prior to substantial boiling and (2) reduces power prior to substantial boiling as set forth in the specific claimed features set forth above. Even if the device taught in the reference could detect a threshold amount of steam in the tissue and reduce power, the reference is silent as how to determine the threshold amount. Therefore, the Nardella ‘281 Patent does not anticipate claim 25.

Furthermore, the prior art does not make obvious a modification to the method of the Nardella ‘281 Patent to obtain the features of claim 25. As pointed out in the Final Office Action, the Nardella ‘281 Patent is concerned with steam levels and does not include a teaching on boiling. Further, there is no recognition in the prior art of sensing vibrations prior to substantial boiling and reducing power prior to substantial boiling provides an advantageous method to reducing cell damage. Accordingly, Appellants submit that independent claim 25 is patentably distinguishable from the Nardella ‘281 Patent.

Claims 26 and 28-33 depend from independent claim 25 and include all of the features of the patentable independent claim. By virtue of their dependency to claim 25, claims 26 and 28-33 are also patentably distinguishable from the Nardella ‘281 Patent. Thus, Appellants request that the rejection of claims 25, 26 and 28-33 under 35 U.S.C. 102(b) be reversed and the claims be allowed.

II. Rejection of Claims 25-26 and 28-33 under 35 U.S.C. 102(b) as being unpatentable over the Nardella ‘281 Patent in view of the Nardella ‘193 Patent.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Nardella ‘281 Patent in view of the Nardella ‘193 Patent”. Claim 27 depends from independent claim 25, which has been demonstrated above to be patentably distinguishable from the Nardella ‘281 Patent. As described above, the Nardella ‘281 Patent does not include the claim features of sensing vibration “prior to substantial boiling” set forth in claim 25. These features are also missing from the Nardella ‘193 Patent. Because the claimed features are missing from each of the references separately, they would be missing from any proposed combination of the references. Appellants submit that claim 27, by virtue of its dependency from claim 25, is thus patentably distinguishable from the combination of references. Accordingly, Appellants request that the rejection of claim 27 under 35 U.S.C. 103(a) be reversed and the claim be allowed.

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

CONCLUSION

In view of the above, Appellant respectfully submits that pending claims 25-33 are in form for allowance and are not taught or made obvious by the prior art of record. Therefore, reversal of the rejections of claims 25-33 is respectfully requested.

Any inquiry regarding this Appeal Brief to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

May 13, 2011

Dated

/Rudolph P. Hofmann/

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Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

CLAIMS APPENDIX

1-24 (Canceled)

25. A method of ablating organic tissue, comprising:
 - positioning an electrode adjacent the organic tissue;
 - supplying electrical power to the electrode to effect ablation of the organic tissue;
 - sensing with a sensor positioned adjacent the electrode the vibration of the organic tissue being ablated wherein the vibration is self-generated in the organic tissue in response to the ablation and the vibration occurs prior to substantial boiling to water in the organic tissue; and
 - reducing power to the electrode when the vibration reaches a given value.
26. The method of claim 25, further comprising:
 - halting the power when the vibration reaches a given value.
27. The method of claim 25, further comprising:
 - supplying fluid from a fluid supply to the tissue; and
 - halting the fluid supply when the vibration reaches a given value.
28. The method of claim 25 further comprising:
 - sending a signal from the sensor to a switch to reduce the power.
29. The method of claim 25, further comprising:
 - providing output from an output device when the vibration reaches a given value.
30. The method of claim 29 further comprising:
 - sending a signal from the sensor to the output device; and sending an indicator signal from the output device.
31. The method of claim 25 wherein the sensor is a piezoelectric crystal.

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

32. The method of claim 25 wherein the sensor is a piezoelectric polymer.

33. The method of claim 25 wherein the sensor is integrated with the electrode.

34. – 61. (Cancelled)

62. – 79. (Withdrawn)

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

EVIDENCE APPENDIX

None.

Appeal Brief to the Board of Patent Appeals and Interferences

Serial No. 10/792,178

Dkt.: P008575.06/M190.253.101

Filing Date: March 3, 2004

Title: VIBRATION SENSITIVE ABLATION DEVICE AND METHOD

RELATED PROCEEDINGS APPENDIX

A copy of the Panel Decision mailed on September 1, 2010, is attached.